# Environmental Science and Technology Program

# Quality Management Plan

Approved by:

Original signed by B.R. Erdal

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Bruce R. Erdal
Program Manager

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Date

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## Quality Policy Statement

Integrated with other Environmental Management (EM) activities, the Environmental Science and Technology Program (E/ST) will develop the model technology development program, supply environmental restoration and waste management activities with innovative, cost-effective,timely solutions to their environmental issues, and generally apply technological expertise to efficient, well-managed resolution of environmental impacts.

Work performed by E/ST will be in accordance with requirements stated in this E/ST Program Quality Management Plan (PQMP) and the EM Strategic Plan at Los Alamos National Laboratory.

E/ST will apply the requirements stated in this PQMP to appropriate E/ST activities, thereby ensuring that E/ST delivers products and services of the highest quality on schedule and within budget. E/ST will use a graded approach, commensurate with the risk and complexity of the work to be performed, to establish and apply requirements. Management will motivate and empower personnel, provide appropriate resources, ensure proper training, continually assess and improve performance, and determine which requirements apply to their area of responsibility.

*The Environmental Science and Technology (E/TST program will conduct all work in accordance with requirements stated in this Program Quality Management Plan and the E Division Strategic Plan at Los Alamos National Laboratory*

## Quality Program

The Laboratory Quality Assurance Management Plan details the requirements for the contents of this plan; the PQMP's structure is based on the criteria set forth in Title 10 Code of Federal Regulation Part 830. Specific definitions are given in Appendix A.

The PQMP imposes a minimum level of quality requirements that apply to E/ST employees and those performing work for E/ST, including those working under another quality program. Appropriate standards, wherever applicable, will be used to develop and implement quality programs. Quality programs will describe management processes, which include planning, scheduling, and resource considerations.

Appendix B shows the E/ST organizational structure. E/ST lines of authority begin at the program manager level. Technical divisions provide matrix support to E/ST so that it can accomplish its missions.

This PQMP describes the requirements for E/ST's conduct of operations, such as organizational structure, responsibilities, interfaces, and work performed. The E/ST PQMP and implementing procedures are approved by the E/ST program manager.

Numerous interfaces take place between E/ST and other Laboratory organizations, such as: Business Operations (BUS); Environment, Safety & Health (ESH); Facilities, Security & Safeguards (FSS); Human Resources (HR); Earth and Environmental Sciences (EES); Chemistry (C); and Engineering Sciences & Applications (ESA); among others. As appropriate, E/ST elements may adopt quality programs from performing organizations, including contractors.

*All work conducted with EM/TD must conform with applicable requirements, including those stipulated by the Department of Energy (DOE), Atomic Energy Act, Environmental Protection Agency, Occupational Safety and Health Administration, Department of Transportation, State of New Mexico, and Los Alamos National Laboratory. This purpose of this PQMP is to ensure that E/ST projects comply with these requirements through a formal and consistent management process.p*

*EM/TD project personnel must be qualified to perform assigned tasks; E/ST project personnel will maintain records to document qualification, including relevant education and experience.*

*Personnel Development*

Training will focus on ensuring that employees understand safety and quality, with emphasis on "doing the job right the first time." Training classes will demonstrate the interdependence of work activities, emphasizing the employee's role in the overall program.

Personnel will receive the necessary orientation and training to achieve initial proficiency, with continuing training to ensure that job proficiency is maintained. E/ST encourages professional development opportunities beyond basic qualification training.

Supervisors are responsible for establishing and documenting job descriptions for each position, including education and previous experience required. They also will ensure that their employees receive orientation to their respective job duties and responsibilities. Reorientation will be conducted, as necessary, to adapt to changes in an employee's assigned work.

Supervisors will conduct annual performance appraisals for the employees under their supervision. In accordance with Laboratory requirements, supervisors will evaluate employees on their technical work and their attention to environment, safety, and health (ES&H) requirements.

*E/ST advocates the principles of continuous improvement and encourages personnel to identify and suggest improvements.*

*Quality Improvement*

All levels of management foster the continuous improvement culture, which assumes that all processes can be improved. The E/ST quality improvement process will prevent problems and improve the quality of products and services.

E/ST will identify and document items and processes that fail to meet established requirements. E/ST will analyze then resolve the deficiencies found in such items and processes. The effort expended on deficient items and processes will be commensurate with the importance or significance of the problem.

Improvement planning and problem prevention will be implemented at the appropriate level. Teams to address process improvement will be approved by the highest level of management of the organization responsible for the process—process owners and management will be responsible for implementing improvements. Improvement tools/methods include peer reviews; independent technical assessments; benchmarking; re-engineering; design reviews; probabilistic risk assessment; safety analysis; cause analysis; reliability, availability, and maintainability analyses; and trending.

*E/ST will control the preparation, review, approval, issuance, use, and revision of documents commensurate with their importance. E/ST will distribute controlled documents to personnel conducting the work.*

*Documents and Records*

The document control process will help E/ST distribute and track documents that describe work to be performed. Controlled documents consist of plans, procedures, instructions, specifications, and drawings that define or demonstrate requirements necessary toward accomplishing activities. Controlled documents should not be confused with records or documents generated by activities conducted within E/ST. E/ST will conduct document control pursuant to implementing procedures developed by the program/operation and consistent with

Laboratory guidance (*e.g.*, the Laboratory Quality Assurance Guidebook).

Records consist of completed documents resulting from activities directly related to procedure implementation—they are the primary focus of records management system activities. Each applicable implementing procedure will list documents that will be submitted to the records management system as a result of the process defined in the procedure.

Operations will develop and implement procedures for records management systems consistent with Laboratory guidance. These procedures/systems will include requirements for records disposition, storage, and retrievability.

E/ST personnel must maintain adequate documentation of their work

in sufficient detail to prove authorship, authenticity, and originality. Records generated as a result of Laboratory-sponsored work are the property of the Laboratory.

The user will determine the appropriate or suitable use for software. Users must obtain the latest version of software. They also must provide proper documentation, user guides and manuals, source change control, and software verification and validation.

E/ST will develop and implement a procedure to prepare, review, approve, and distribute procedures that meet the requirements of this EM QMP and the Laboratory Quality Assurance Management Plan.

*Work Processes*

*E/ST project personnel will establish and implement quality requirements that optimize the efficiency and effectiveness of work processes. If appropriate, E/STwill document repetitive processes into a procedure that describes the steps necessary to comply with applicable requirements such as HS&E.*

Each operation must plan work and impose appropriate controls or other requirements. To determine which controls or requirements to impose, operations will use a graded approach that considers the complexity and importance of the work, potential risk to employee safety and the environment, required accuracy and precision of data to be collected, and impacts to cost and schedule if reworking is necessary.

E/ST performs a spectrum of work processes. Each operation must plan, authorize, and accomplish each work plan according to requirements established in this PQMP. Planned work will address appropriate technical standards, instructions, procedures, or other guidelines commensurate with work complexity and risk.

Operations that handle items or samples must develop and implement procedures to properly control/manage (e.g., handling, storing, and shipping) them based on complexity and risk.

Each operation will develop procedures to ensure that proper calibration, measurement, accountability, and use of equipment that monitors or conducts data collection, controls process parameters that affect the quality of an item's characteristics, or an instrument used for in-process or final inspection. Personnel will calibrate measuring and test equipment at specified intervals based on the equipment's required accuracy, intended use, frequency of use, item stability characteristics, or other conditions affecting performance.

E/ST operations will include maintenance activities that reduce the impact of equipment malfunction when operating within established ES&H standards. Preventive maintenance programs will be established that take into consideration operational economics and safety concerns (*e.g.*, the hazardous consequences of equipment failure) and the value of lost time and equipment weighed against preventive maintenance costs.

E/ST operations will address health and safety issues for all aspects of defined program activities or work processes and will establish safety requirements that ensure employee understanding/training and responsibilities.

*Not only will E/ST project personnel conduct design activities in accordance with established and approved procedures, they also will incorporate and implement sound engineering/scientific principles and appropriate standards (e.g., DOE Order 6430.lA and Laboratory Quality Management Plan).*

*Design*

E/ST will specify and approve design inputs on a timely basis. These inputs will consist of a level of detail required to effectively carry out design activities. E/ST will conduct informal design reviews, including design verifications and evaluation of design changes, to ensure that the design input is correctly incorporated into the design output. Changes to design will undergo the same review as the original design.

*Procurement*

E/ST will plan and implement the procurement of items or services in a way that ensures that the proper items or services are selected for the intended use and that the items or services received meet selection criteria.

*When required, programs/operations will establish procedures to conduct planning and inspection that meet the requirements of the Laboratory Quality Assurance Management Plan.*

*Inspection and Acceptance Testing*

Planning procedures will identify the item or service characteristics and processes to be inspected and the organization to perform the inspection. The level of inspection and degree of inspection personnel independence will be based on the risk and complexity involved and will be specified in the procedures.

When required, programs/operations will establish procedures to conduct proper acceptance testing that meets the requirements of the Laboratory Quality Assurance Management Plan.

*E/ST project personnel will establish and implement planned and periodic management assessments to evaluate quality assurance program implementation.*

*Management Assessment*

Deficiencies identified during management assessments will be documented, reported to the appropriate level of management, and corrected. E/ST will use assessment results to continuously improve the quality and efficiency of management and operations.

Overall management assessment responsibilities will rest with the program director. The process will include direct participation from supervisors/managers through all management levels and comply with requirements of the Laboratory Quality Assurance Management Plan.

E/ST will implement corrective action as necessary and will follow up to evaluate the effectiveness of management actions.

*E/ST project personnel will conduct planned and scheduled assessments to verify compliance with quality management plans.*

*Independent Assessment*

Trained personnel who have no direct responsibility for the areas they are assessing will conduct these assessments; these individuals or

teams will have sufficient authority and freedom from the line to carry out all responsibilities. Personnel performing independent assessments will be technically knowledgeable.

Assessments will use criteria that evaluate acceptable work performance and promote continuous improvement. Assessment schedules and resource allocations will be based on the status; risk; and complexity

of the item, service, or process being assessed.

Independent assessors will monitor work performance, identify abnormal performance and potential problem precursors, identify improvement opportunities, report results to the level of management that has authority to effect change, and verify resolution of problems.

Findings from assessments will be documented, tracked, and resolved.

## APPENDIX A: Definitions

*Definitions*

**Assessment or Audit:** A planned and documented verification activity that involves investigation, examination, or evaluation of objective evidence to determine the adequacy of and compliance with established implementing documents and the effectiveness of implementation.

**Characteristic:** A property of a work product that is distinct, describable, and measurable.

**Corrective Action:** Measures taken to rectify deficiencies and, where necessary, to preclude repetition.

**Document:** Any written or pictorial information that describes, defines, specifies, reports, or certifies activities, requirements, procedures, or results.

**Document Control:** Ensuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity

is performed.

**Guideline:** A suggested practice that is not mandatory in programs intended to comply with a standard.

**Inspection**: Examining or measuring to verify whether an item or activity conforms to specified requirements.

**Item:** An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material module, part, structure, subassembly, subsystem, system, or unit.

**Measuring and Test Equipment:** Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

**Orientation:** Instruction that an immediate supervisor gives to an employee that provides him or her with an overview of the organizational structure and the employee's duties and responsibilities.

**Procedure:** A document that specifies or describes how an activity must be performed.

**Qualification (Personnel):** The characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

**Quality Assurance (Quality):** Those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

**Record:** A completed document that furnishes evidence of the quality of items and/or activities.

*Definitions*

**Rework:** The process by which an item is made to conform to original requirements by completion or correction action documents for the purpose of determining the presence of repetitive problems adverse to quality.

**Sample:** An all-inclusive term used to define solid, liquid, or gaseous materials selected as being representative of a specific item, medium, or process.

**Service:** Performing activities such as design, fabrication, inspection, nondestructive examination, repair, or installation.

**Testing:** An element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

**Trending:** The categorical grouping and analysis of corrective action documents for the purpose of determining the presence of repetitive problems adverse to quality.

**Verification:** The act of reviewing, inspector testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

**APPENDIX B: EM/Technology Tevelopment Program Office**